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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,643	08/21/2003	Adrian Liem	4-32682A	8789

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,643	LIEM ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 20, 2006 has been entered. Claims 1-20 and 23-35 have been cancelled. Claims 21-22 are pending and under examination. Applicant's submission of Attachment A and B filed March 20, 2006 are acknowledged.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. *This is a new matter rejection.* The amendment filed June 21, 2005 introduced new matter into the claims.

The claims have been amended to recite, "...non-concentrated..." and "...unconcentrated..." 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant's amendment introduces a "new matter" that is not supported by the original disclosure. The specification is enabled for a killed whole cell culture of *Fusobacterium necrophorum* (page 4). Applicant has failed to direct the Examiner as to where in the instant specification the support for this amendment ("non-concentrated" or "unconcentrated") is specifically shown and/or implied. The Examiner has reviewed the instant specification and has failed to find the support for the amendment. Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-22 recite "...non-concentrated" and "unconcentrated" It is unclear as to what the applicant is referring? Does Applicant mean an intact whole cell? Clarification is required.

Based on the New Matter Rejection set forth in paragraph 3 above the following art rejections are maintained.

Rejections Maintained

5. The rejection under 35 U.S.C. 103(a) over claims 21-22 is maintained for the reasons set forth pages 3-5 paragraph 5 of the Final Office Action.

The rejection was on the grounds that Garcia et al teach a method of preventing liver abscesses in bovines (see the Abstract). Garcia et al teach the *Sphaerophous necrophorus* was isolated from bovine (page 223). Garcia et al teach that the *S. necrophorus* preparations used to make the vaccine compositions were treated (inactivated) using formaldehyde (page 223). Garcia et al teach that the vaccine composition was formulated using alum (page 223). Garcia et al teach that the antigen suspension was adjusted to 1 mg/ml protein (page 223). Garcia et al teach that the doses range form 1.0 to 20.0 ml (page 223). Garcia et al teach that calves were injected subcutaneously in the neck (page 223). Garcia et al teach that claves were given an initial dose of the vaccine and received a booster injection of dose 0.1 mg/ml protein in 5.0 ml of saline (page 224). Garcia et al teach that the vaccine composition comprising *S. necrophorus* cytoplasmic toxoid was the most effective in protecting against liver abscesses due to *S. necrophorus* infection (page 225).

Garcia et al do not teach preventing footrot.

Emery et al teach that the gram-negative *Fusobacterium necroporum* causes foot abscesses and live abscesses in ruminants (page 43). Emery et al teach that *Fusobacterium necrophorum* can be cultured on suitable medium for a period of time up to 18 hours (page 44). Therefore, the prior art teaches the claim limitation "...successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture" is taught by the prior art.

It would be *prima facie* obvious at the time the invention was made to use a vaccine composition comprising *Fusobacterium necrophorum* in a method of preventing footrot or liver abscesses because Emery et al teach that the association between *Fusobacterium necrophorum* specifically, the strain of biotype AB and lesion of foot abscesses in cattle implies that potential vaccine against infection should be sought from these strains of *F. necrophorum* (page 46). It would expected barring evidence to the contrary that vaccine composition comprising *Fusobacterium necrophorum* would be

effective in preventing infections caused by *F. necrophorum* because Garcia et al has shown that *F. necrophorum* is effective against preventing *F. necrophorum* infections.

Applicant's arguments

A) Applicant urges that Garcia et al do not teach "whole cell cultures" to prepare the vaccines used in the method of preventing footrot and liver abscesses in bovines. Applicant urges that sonication breaks open the cells.

B) Applicant refers to Table 1, page 225 of the prior art and asserts that the sonicated toxoid had more abscesses per liver than the two different cytoplasmic toxoids. Applicant urges that Garcia et al teach away from the use of whole cultures in the vaccine compositions used in the claimed method and one of skill in the art would not recognize that Garcia et al teach vaccine compositions prepared from whole cell cultures.

C) Applicant urges that Emery et al do not provide any remedy for the failure on the part of Garcia.

Examiner's Response to Applicant's Arguments

A) It is the Examiner's position that Garcia et al teach that certain vaccine compositions used in the invention were prepared from sonicated, unfractionated cells (whole cells) (page 223, 2nd column). Therefore, one of skill in the art would recognize

that Garcia et al teach that vaccines used in the method were prepared using whole cell cultures.

B) It is the Examiner's position that the combination of references teach the claimed invention. Thus, the combination of references do not teach away from the claimed invention. To address Applicant's comments regarding Table 1, page 225 of the prior art, it should be noted that the sonicated toxoids in Table 1 refer to unfractionated cells (whole cells) (page 223, 2nd column).

C) It should be remembered that it is the combination of references that teach the claimed invention. Thus, Emery et al teach that *Fusobacterium necroporum* causes foot abscesses and live abscesses in ruminants. Therefore, this reference established a nexus between *Fusobacterium necroporum* and foot abscesses in ruminants. It is the Examiner's position that there is nothing on the record to suggest that the combination of references do not teach the claimed invention.

6. The rejection under 35 U.S.C. 103(a) over claims 21-22 is maintained for the reasons set forth pages 6-8 paragraph 6 of the Final Office Action.

The rejection was on the grounds that Garcia et al teach a method of preventing liver abscesses in bovines (see the Abstract). Garcia et al teach the *Sphaerophous necrophorus* was isolated from bovine (page 223). Garcia et al teach that the *S. necrophorus* preparations used to make the vaccine compositions were treated (inactivated) using formaldehyde (page 223). Garcia et al teach that the vaccine composition was formulated using alum (page 223). Garcia et al teach that the antigen suspension was adjusted to 1 mg/ml protein (page 223). Garcia et al teach that the doses range form 1.0 to 20.0 ml (page 223). Garcia et al teach that calves were

injected subcutaneously in the neck (page 223). Garcia et al teach that claves were given an initial dose of the vaccine and received a booster injection of dose 0.1 mg/ml protein in 5.0 ml of saline (page 224). Garcia et al teach that the vaccine composition comprising *S. necrophorus* cytoplasmic toxoid was the most effective in protecting against liver abscesses due to *S. necrophorus* infection (page 225).

Garcia et al do not teach preventing footrot.

Clark et al teach that *Fusobacterium necrophorum* is effective in preventing interdigital necrobacillosis (footrot) (see the Abstract). Clark et al teach that vaccine compositions contained whole cultures, cytoplasmic fractions, cell-free supernatants or killed cells formulated in a mineral oil adjuvant (page 107-108). Clark et al teach that vaccine compositions comprising culture supernatants provided the most protection against footrot in cattle (see the Abstract and page 109). Clark et al teach that *Fusobacterium necrophorum* can be cultured on suitable medium for a period of time up to 18 hours (page 107). Therefore, the prior art teaches the claim limitation "...successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture" is taught by the prior art.

It would be *prima facie* obvious at the time the invention was made to add the vaccine compositions comprising culture supernatants of *Fusobacterium necrophorum* as taught by Clark et al to the vaccine compositions comprising *Fusobacterium necrophorum* cytoplasmic toxoid of Garcia et al to be used to prevent footrot and liver abscesses in cattle because Garcia et al has demonstrated that compositions comprising *F. necrophorum* cytoplasmic toxoid are effective at preventing liver abscesses in cattle and Clark et al has demonstrated that compositions comprising *F. necrophorum* culture supernatants are effective in preventing footrot in cattle. It would expected barring evidence to the contrary that vaccine compositions comprising *F. necrophorum* cytoplasmic toxoid and culture supernatants would be effective in preventing infections caused by *F. necrophorum*.

Applicant's arguments

A) Applicant urges that Clark et al uses whole cells that have been concentrated

Applicant urges that the concentrated whole cell vaccine provided 25% protection,

while the cytoplasmic fraction vaccine provided 37.5% protection. Applicant urges that

Clark appears to teach away from using whole cell vaccines. Applicant urges that Clark

do not teach non-concentrated whole cell vaccines.

B) Applicant urges that Garcia et al teach away from the used of whole cultures in the vaccine compositions used in the claimed and one skill in the art would not recognize that Garcia et al teach vaccine compositions prepared from whole cell cultures.

C) Applicant urges that the claimed invention provides surprising results in that the methods protect bovine from infections of *F. necrophorum*. Applicant urges that the combination of references do no teach the claimed invention since neither reference teaches non-concentrated whole cells.

In view of all of the above, this rejection is maintained.

Examiner's Response to Applicant's Arguments

A) It should be remembered that Clark et al teach vaccine compositions comprising *Fusobacterium necroporum* whole cell cultures (page 107, 2nd column). Clark et al teach also teach that *Fusobacterium necroporum* causes interdigital necrobacillosis Thus, this reference established a nexus between *Fusobacterium necroporum* and interdigital necrobacillosis in cattle. It should be noted that Clark et al teach that group 1 was immunized with vaccines comprising whole cell cultures and provided protection against interdigital necrobacillosis (page 109, 2nd column). It is the Examiner's position that there is nothing on the record to suggest that the combination of references do not teach the claimed invention. To address, Applicant's comments regarding protection of

the vaccine, it should be noted that the claims do not require that a certain level of protection be obtained.

B) To address Applicant comments regarding Garcia et al, Garcia et al teach that certain vaccine compositions used in the invention were prepared from sonicated, unfractionated cells (whole cells) (page 223, 2nd column). Therefore, one of skill in the art would recognize that Garcia et al teach that vaccines used in the method were prepared using whole cell cultures.

C) Garcia et al and Clark et al both teach vaccine compositions comprising whole cell cultures. Thus, the combination of references do not teach away from the claimed invention. To address Applicant comments regarding surprising results, it should be noted that Clark et al teach on page 109 that whole cell cultures provide protection against interdigital necrobacillosis (footrot).

In view of all of the above, this rejection is maintained.

Status of Claims

7. No claims are allowed.

Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272–1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (57`) 572-8300.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 20, 2006

NITA MINNIFIELD
PRIMARY EXAMINER